

REMARKS

Claims 1 - 8 are pending in the present application. The Examiner rejects Claims 1 - 8 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Claims Comply with the Written Description Requirement

In the response filed on 7/5/05, the Applicants provided the Declaration of Dr. Allen Comer. Dr. Comer's declaration states that a number of irritant responsive genes and promoters were known as of the March 2001 priority date of the application. The Applicants further distinguish the present case from *Eli Lilly* in that the Applicants have provided factual evidence of what was known to those of skill in the art and the fact that the present invention claims a method of use, rather than compositions of matter¹. In the present Office Action, the Examiner fails to consider the Declaration of Dr. Comer. The Examiner further fails to rebut the Applicants' arguments of record summarized above. The Examiner has simply repeated his earlier arguments as to why the Claims allegedly lack written description. The Applicants will be left with no choice but to appeal these rejections if the proper weight is not given to the Comer Declaration and the claims allowed.

The Examiner continues to rely upon the holding of *Eli Lilly* even though the holding and facts of *Eli Lilly* are not applicable to this case. In particular, as established by the Comer Declaration and the specification, the present invention utilizes irritant responsive reporter gene constructs comprising known promoters. *Eli Lilly* addressed whether the written description requirement was met for claims to human insulin cDNA when no sequence for the cDNA was provided and the sequence was not known. In the present case, the sequences for the promoters in the reporter gene construct are known and examples were provided in the specification. The Federal Circuit recently addressed a similar situation in *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 65 U.S.P.Q.2d 1385 (Fed. Cir. 2003). The issue there was whether an adequate written description had been provided for expression of erythropoietin in all vertebrate and mammalian cells where specific examples had only been provided in two species of cells. The Federal Circuit held that "Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case

¹ The Applicants' arguments are not repeated in detail here but can be found in the response to Office Action submitted by the Applicants on 7/5/05.

because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend.” The Federal Circuit went on to state: “Indeed, [the patent owner’s] patents appear to satisfy the sequence requirement in Eli Lilly insofar as Figure 6 of the patents expressly discloses the complete (albeit slightly incorrect) sequence of the human genomic EPO DNA and the encoded DNA.” In the instant case, the components of the claim term at issue (i.e., irritant responsive reporter gene construct) are not new or unknown biological materials. As established by the Comer Declaration, the components, including the promoters were known in the art. Moreover, the sequences of two of the known promoters were provided in the specification. Since these components are known, there is no chance they could be miscomprehended by a person of ordinary skill in the art.

The Federal Circuit has stated time and time again that rebuttal evidence of one skilled in the art cannot be dismissed by the Office without consideration. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

In *In re Alton*, the applicants submitted a declaration in order to rebut a *prima facie* case of inadequate written description by the Board of Appeals in an earlier appeal. *Id.* at 1173. Instead of addressing the arguments presented in the declaration, the Examiner dismissed the declaration as opinion evidence that was entitled to little weight. *Id.* at 1173-745. The Federal Circuit remanded the case to the Board, holding that the Board committed error in both viewing the declaration as opinion evidence and dismissing the declaration "without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case" of unpatentability. *Id.* at 1174. These bases for reversal were independent. With respect to failure to provide an adequate explanation of why the declaration failed to rebut the *prima facie* case, the Federal Circuit found that:

In sum, the examiner dismissed the Wall declaration and provided only conclusory statements as to why the declaration did not show that a person skilled in the art would realize that Alton had possession of the claimed subject matter in 1983.

Id. at 1176. In particular, the Federal Circuit held that the examiner failed to address specific points made in the declaration concerning modifications of the amino acids sequence of protein.

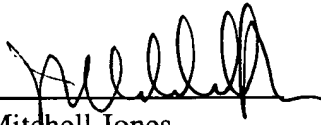
Id.

In re Alton is directly applicable to the present facts. Instead of addressing the arguments presented in the Comer Declaration, the Office has provided only conclusory statements and failed to address the particular evidence offered in the Declaration. As a result, Applicants respectfully request that the Examiner reconsider the evidence offered in the Comer Declaration.

CONCLUSION

All grounds of rejection and objection of the Office Action of March 21, 2006 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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